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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/542,821

10/21/2005

Luis Octavio Guisasola

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11/26/2008

INTELLECTUAL PROPERTY / TECHNOLOGY LAW

PO BOX 14329

RESEARCH TRIANGLE PARK, NC 27709

EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

11/26/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/542,821	<b>Applicant(s)</b> GUISASOLA ET AL.	
	<b>Examiner</b> Barbara P. Badio	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/3/2006</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

**First Office Action on the Merits**

***Priority***

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Spain on January 22, 2003. It is noted, however, that applicant has not filed a certified copy of the foreign application as required by 35 U.S.C. 119(b).

***Claim Rejections - 35 USC § 101***

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claim 11 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claim recites a "use" without setting forth any steps involved in the process and, thus, results in an improper definition of a process, i.e., results in a claim that is not a proper process claim under 35 USC § 101 (see MPEP § 2173.05(q)).

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite for the following reasons:

Claim 11 is indefinite because it merely recites a "use" without any active, positive steps delimiting how this use is actually practiced and, thus, it is unclear what process is encompassed by the claimed invention (see MPEP § 2173.05(q)). For the purpose of art rejection, the claim is interpreted as being drawn to a method of obtaining 17 $\alpha$ -acetoxy-11 $\beta$ -(4-N,N-dimethylaminophenyl)-19-norpregna-4,9(10)-diene-3,20-dione (VA-2914) by purifying raw VA-2914 via the production of the corresponding isopropanol hemisolvate.

Claim 12 lacks a period and, thus, the skilled artisan would be unable to determine the metes and bound of the claimed invention

### ***Double Patenting***

6. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

7. Claim 12 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 25 of copending Application No. 10/542,580. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 5, 8, 9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al. (WO 96/30390).

Kim et al. teaches a process for the production of 17 $\alpha$ -acetoxy-11 $\beta$ -(4-N,N-dimethylaminophenyl)-19-norpregna-4,9(10)-diene-3,20-dione (VA-2914) which includes purification of the said compound by (a) dissolution and evaporation in isopropyl alcohol and obtaining a solid which retained isopropyl alcohol followed by dissolving in ethyl acetate, evaporation and crystallization from ether (see the entire article, especially page 23, Example 7, lines 24-36). The process and the solvate taught by the reference are encompassed by the instant claims.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 2-4, 6, 7, 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (WO 96/30390) as applied to claim 1 above, and further in view of Cook et al. (WO 99/45022).

As stated above in #8, Kim et al. teaches a process for the production of 17 $\alpha$ -acetoxy-11 $\beta$ -(4-N,N-dimethylaminophenyl)-19-norpregna-4,9(10)-diene-3,20-dione (VA-2914) which includes purification of the said compound by (a) dissolution and evaporation in isopropyl alcohol and obtaining a solid which retained isopropyl alcohol followed by dissolving in ethyl acetate, evaporation and crystallization from ether (see the entire article, especially page 23, Example 7, lines 24-36).

Claims 2-4 and 10 differ from the reference by reciting crystallization of the isopropanol hemisolvate by cooling, reaction conditions for said crystallization process and filtration of the solid.

Claim 6 differ from the reference by reciting the conversion of the isopropanol hemisolvate into 17 $\alpha$ -acetoxy-11 $\beta$ -(4-N,N-dimethylaminophenyl)-19-norpregna-4,9(10)-diene-3,20-dione (VA-2914) by recrystallization using ethanol/water or ethyl ether.

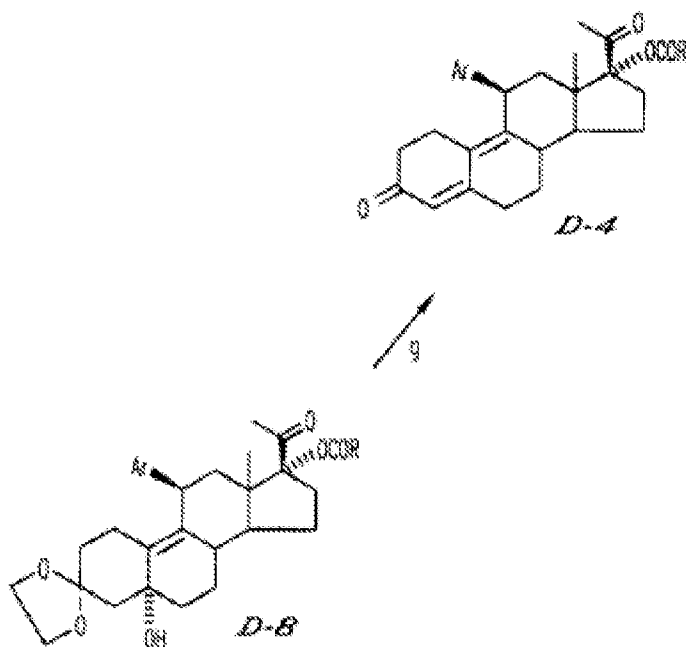
However, crystallization by dissolution and cooling, instead of evaporation, is well known in the art and, thus, is not a patentable distinction absent a showing of criticality.

Finding the reaction condition(s), temperatures for complete dissolution and crystallization as well as other solvents for crystallization of VA-2914 from the hemisolvate would require only routine experimentation which would have been within the level of skill of the ordinary artisan in the art at the time of the present invention. Additionally, Kim teaches the use of ether but is silent as to which ether is utilized and, thus, the use of ether in the crystallization process is *prima facie* obvious.

Claim 7 differs from the reference by reciting a process for obtaining raw 17 $\alpha$ -acetoxy-11 $\beta$ -(4-N,N-dimethylaminophenyl)-19-norpregna-4,9(10)-diene-3,20-dione (VA-2914) via acid hydrolysis of 3,3-(1,2-ethanedioxy)-5 $\alpha$ -hydroxy-11 $\beta$ -(4,4-dimethylaminophenyl)-17 $\alpha$ -acetoxy-19-norpregna-9-ene-20-one.

Claim 12 differs from the reference by reciting the compound 3,3-(1,2-ethanedioxy)-5 $\alpha$ -hydroxy-11 $\beta$ -(4,4-dimethylaminophenyl)-17 $\alpha$ -acetoxy-19-norpregna-9-ene-20-one.

However, Cook et al. teaches similar compounds, i.e., 20-keto-11 $\beta$ -arylsteroids and processes for their production (see the entire article, especially Figures 1 and 4). In Figure 4, Cook shows the following reaction:



wherein D-4 is obtained from D-8 by acid hydrolysis. Cook teaches a genus of compounds of formula (III), which encompasses D-8 and the instantly claimed 3,3-(1,2-ethanedioxy)-5 $\alpha$ -hydroxy-11 $\beta$ -(4,4-dimethylaminophenyl)-17 $\alpha$ -acetoxy-19-norpregna-9-ene-20-one (see page 84, claim 18). That is, Cook teaches Ar can be 4,4-dimethylaminophenyl and R as alkyl and exemplifies D-4 as 17 $\alpha$ -propionyloxy-11 $\beta$ -(4-N,N-dimethylaminophenyl)-19-norpregna-4,9(10)-diene-3,20-dione (see for example, page 28, line 11, Example 5). Therefore, it would have been obvious to the skilled artisan in the art to make 17 $\alpha$ -acetoxy-11 $\beta$ -(4-N,N-dimethylaminophenyl)-19-norpregna-4,9(10)-diene-3,20-dione taught by Kim et al. from the corresponding 3,3-(1,2-ethanedioxy)-5 $\alpha$ -hydroxy-11 $\beta$ -(4,4-dimethylaminophenyl)-17 $\alpha$ -acetoxy-19-norpregna-9-ene-20-one via acid hydrolysis as



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taught by Cook et al. with the reasonable expectation of obtaining the desired end compound.

### ***Telephone Inquiry***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio/  
Primary Examiner, Art Unit 1612